

REMARKS

The independent claims have been amended above to emphasize that the pentane -1,5-diol was the multiple-resistant bacteria bacteriostatic agent.

In evaluating the claims under consideration vis-à-vis the prior art, it is important to recognize that, as stated on the first page of this application, “multiple-resistant” means resistance against at least one antibiotic known to be effective against a corresponding non-resistant strain. Even if the application had not so stated, the same understanding would be shared by those of ordinary skill in this art. For example, the subcommittee on methodology of the Swedish Reference Group for Antibiotics uses the following working definition of multiple-resistant bacteria: “a bacterium with such resistance that established therapeutic alternatives no longer can be used as in treatment and prophylaxis.” (Definition in Swedish can be found at www.srga.org/mrb/mrbdef.html). The amount of multiple-resistant bacteria is relatively small. For example, multiple resistant *S. aureus* in the Swedish hospital environment has been found in a frequency of less than 1%. *Id.* Nevertheless, these so-called “superbugs” are becoming more prevalent.

It will be appreciated that just because a given antibiotic may be active against a bacteria which is not multiple-resistant does not provide any reasonable basis for believing it will be effective against a strain of the same bacteria which has become multiple-resistant. Indeed, the very definition of “multiple-resistant” is that the antibiotic has lost antibiotic activity. As a result, a skilled person would not consider investigating antibacterial agents only known to be active against non-multi-resistant bacteria when desiring to inhibit multiple-resistant bacteria since that is a contradiction

in terms. The art is replete with antibiotics which have failed to provide an inhibitive effect with respect to multiple-resistant bacteria. Indeed, the problem of multiple-resistant bacteria in and of itself would lead the skilled person away from testing substances which have only been proven to be antibacterial against non-resistant strains but rather would look to find another agent which had been previously indicated to have at least some effect against multiple-resistant bacteria. To the extent that some antibiotics have shown at least some degree of effect on multiple-resistant bacteria, they do not include any member of the broad class of diols. Accordingly, the artisan would have no reason to even attempt experimentation to see if diols had multiple-resistant bacteria effect, and even if such an investigation was made for some unknown reason, there would be no reasonable expectation of success.

Claims 1, 2, 8-10, 18, and 22 were rejected under 35 U.S.C. § 103 over Swanbeck. This rejection is respectfully traversed.

The Swanbeck patent teaches topical treatment of bacteria and can comprise application of pentane-1,5-diol. However, the "bacteria" referred to in this reference are the non-resistant strains and, as noted above, there is no reasonable expectation that the same agent would be effective against a multiple-resistant strain. Given the fact that there is no reasonable expectation of success, it is respectfully submitted that this rejection is untenable.

Claims 1, 8, 10-13, 20, 22, 23, and 24 were rejected under 35 U.S.C. § 103 over Goodman in view of Tsao. This rejection is also respectfully traversed.

Goodman teaches a topical treatment of a skin condition which contains a nitroimidazole drug as the antimicrobial active agent and the composition contains a water-miscible organic solvent which can be an alkylene glycol. Various suitable alkylene glycols as solvents are disclosed at column 3, lines 34-38. While the Office Action asserts that "pentylene glycol" is 1,5-pentanediol, pentylene glycol is the INCI name for 1,3-pentanediol. Goodman is thus deficient in that it fails to teach or suggest that alkylene glycols have any antibiotic activity, multiple-resistant or otherwise, and also fails to teach or suggest 1,5-pentanediol.

The Tsao reference has been cited for its teaching of the amount of certain alkylene glycols, including 1,5-propylene glycol in a contact lens disinfectant solution. Tsao also fails to teach or suggest that 1,5-pentanediol will have any antibiotic activity, multiple-resistant or otherwise.

The combination of Goodman and Tsao does not teach or suggest that 1,5-pentanediol will have any antibiotic activity against multiple-resistant bacteria and therefore this rejection is untenable and should be withdrawn.

Claims 13 and 25 have been rejected under 35 U.S.C. § 103 over Goodman and Tsao in further view of Noll. The combination of Goodman and Tsao has been discussed above while Noll has been cited only for the use of a detergent. Accordingly, the deficiencies in Goodman and Tsao remain and this rejection is also untenable.

Claims 4, 14, 19, and 21 were rejected under 35 U.S.C. § 103 over Swanbeck in view of Buseman. Swanbeck has been discussed above and Buseman has been cited only to teach adhesive patches. Accordingly, this combination still has the same

deficiencies which have been discussed and cannot serve to render these claims unpatentable.

Claims 1 and 18 were provisionally rejected on the grounds of non-statutory obviousness-type double-patenting over certain claims in co-pending application 11/791,577. Since the rejection is provisional, no response is necessary but it should be observed that the claims of the co-pending application are directed to the possible use of a combination of at least three different diols to inactivate micro-organisms but fails to teach or suggest any of those micro-organisms are multiple-resistant bacteria. None of those claims could even be amended to refer to multiple-resistant bacteria since there is no basis anywhere in the co-pending application for such an amendment. The use of pentane-1,5-diol for the treatment of multiple-resistant bacteria is clearly not obvious over the co-pending application.

In view of the above amendments and remarks, applicant believes the pending application is in condition for allowance.

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Respectfully submitted,

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